Letter of Intent

Dear Evaluation Committee Members,

Please accept this Letter of Intent, to apply for Geoffrey Ogram Memorial Research Grant for my proposed research project entitled "**Micromachined Electronic Nose (e-Nose) Technology – A Paradigm Shift in Lung Cancer Early Detection**". Please note there is no budgetary overlap between the requested fund in this application and any of my currently held or applied for grants.

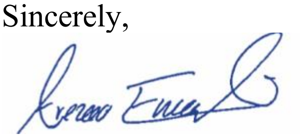
I am Dr. Arezoo Emadi, an Early-Career Associate Professor in the Department of Electrical and Computer Engineering at the University of Windsor, a Core Principal Member of WE-SPARK Research Health Institute, a Principal Member of INSPIRE (Integrated Network for the Surveillance of Pathogens: Increasing Resilience and Capacity in Canada's Pandemic Response), and the Director of eMinds Research Lab (electrical Micro and Nano Devices and Sensors).

My research contributions in biomedical and environmental monitoring field revolve around the area of micro electromechanical systems (MEMS), bio and chemical sensors, and advanced early-stage diagnosis sensor technologies specifically for breast and lung cancer detection applications. I have focused my interdisciplinary efforts on advanced micromachining techniques to enhance sensitivity and performance of new sensors and transducers which has resulted in several patents. A key focus of my research activities is on early-stage diagnostic tools that are demonstrated to be more easily deployable in a multitude of sensing environments with unique capabilities. I have worked and continue to closely work with teams of electrical engineers, mechanical engineers, chemists, biologists, biotechnologists, radiation oncologists, and psychologists on various interdisciplinary projects to create an innovative and robust smart detection system for routine early-stage cancer diagnosis. As such, through strong collaborations our team has gained extensive multidisciplinary skills in developing high-performance electronic sensor systems that are imperative in the success of this proposed research.

Our work on high-sensitive and portable sensors will pave the path for the development of cost-effective and integrated electronic nose systems for early-stage detection of lung cancer. We intend to effectively utilize this generous grant to create preliminary sensor response data to a target lung cancer volatile organic compounds (VOC) profile to demonstrate the advanced functionality of such electronic nose system. We intend to use the demonstrated functionality through this one-year project and apply for NSERC I2I to further bring the technology closer to a fully developed stage.

The seed funding through Geoffrey Ogram Memorial Research Grant will be critical for a leap forward in realization of this proposed paradigm shift in early-stage lung cancer detection. Our proposed technology will result in an easy-to-use handheld diagnostic tool for routine clinical practice, with the potential for wirelessly transmitting data that leads to significant advances in diagnostics and long-term monitoring of patients in remote areas.

Sincerely,



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Summary of the Proposed Research

With early detection widely regarded as a crucial approach to reducing lung cancer mortality rates, the main long-term aim of this work is to develop advanced methodologies using state-of-the-art micromachined electronic nose technology to produce leading transformative and cost-effective early-stage diagnostic tools. This work is inherently interdisciplinary where micro- and nanofabrication techniques in engineering are adapted by oncologists to push the boundaries and limitations of existing cancer diagnostic methods. The short-term aims of this research work are: **Aim A)** studying the existing lung cancer VOC profile in patient exhaled breath. **Aim B)** fabrication, and functionalization of the newly introduced high-performance electronic nose technology as a proof-of-concept.

Aim A) It is shown that during the early stages of lung cancer, patients typically exhale traceable amounts of VOCs in their breath in the range of 10 - 200 ppm. However, studies have indicated that a person without lung cancer will only have the same VOCs in the 10 - 500 ppb range [11-13]. Detection of such VOCs can, therefore, be associated with early-stage lung cancer. Over 42 VOCs have been proposed as candidate lung cancer biomarkers, including aldehyde and ketones such as acetaldehyde and formaldehyde, short-chain alkanes and alkenes like undecane and isopropene, and aromatic compounds like ethylbenzene [14-15]. The growing database of fundamental studies on biomarker indicators of early-stage disease provides a solid starting point for our work to develop a pattern recognition approach to train the proposed electronic nose system. To identify the most effective and reliable target VOC patterns diagnostic of early-stage lung cancer, the common background VOCs in the exhaled breath will be evaluated through collaboration with the PI's partners and network at WE-SPARK Research Health Institute and the resulting profile of major VOCs will be investigated. This list of VOCs will be utilized as a reference in sensor training and characterization during the signal processing and target identification stage.

Aim B) The proposed approach focuses on all aspects of the development of the proposed electronic nose system that for the first time can identify selected lung cancer biomarkers in patient exhaled breath. The system includes three main components: i) a prototype VOC collector [27-28] and a patented high sensitivity micromachined sensor [24-26] developed by the PI's team, ii) a data collector and transmitter, iii) a data processing unit to identify the target biomarkers. The VOC concentrator will be developed based on the existing prototype in PI's lab by optimizing the breathing chamber with a filtration medium for lung cancer associated VOCs and adjusted exhaled rate. The concentrator is electrically controlled and collects the VOCs in a repeatable manner and passes the collected sample over the micromachined sensor. The methodology in this part also includes design, optimization, and fabrication of the novel QCM with Distribution of Area for Improving mass Sensitivity (DAIS) sensor in array format to allow effective identification of target biomarkers in a complex sample of exhaled breath. COMSOL Multiphysics simulation software will be utilized to capitalize on the team's patent application in enhancing the QCM's mass sensitivity with the novel DAIS electrode configurations for a sensor with 5MHz center resonant frequency. A minimum sensitivity enhancement of 20% compared to the conventional QCM will be targeted that will be calculated based on the QCM frequency shift response. The DAIS electrode topology will be optimized to achieve the target sensitivity increase. The analysis results will be utilized to finalize the fabrication process based on the available state-of-the-art fabrication tools. The required fabrication masks will be designed using SoftMEMS. Using the developed masks and the design from the previous step, the DAIS prototype will be fabricated at Angstrom. The process starts by cleaning AT cut quartz crystal and removing contamination, followed by a photolithography step to transfer the electrode pattern to top surface of quartz substrate. Gold and adhesion layers will be utilized as the electrode material and will be deposited on the patterned wafer, followed by the liftoff process. The frequency evaluation will then be conducted on the uncoated sensors under a dry nitrogen environment and a ±5% agreement between measurement and simulation results will be expected.

Through leveraging micromachining fabrication techniques, a sensor data collection system will be developed based on an existing prototype in the PI's team. This prototype accommodates arrays of these functionalized DAIS sensors to provide the needed selectivity and sensitivity for lung cancer VOC signature detection identified from aim A.

This platform further wirelessly transmits the collected data for data processing using a developed principal component analysis (PCA) technique. The fabricated prototype will then be coated using the sensing material previously utilized by the PI's team using validated material deposition techniques. This will allow a uniform deposition on areas as small as 20-40 micrometers in dimension. The uniformity and sensing material full coverage of the functionalized area will be inspected under high resolution using the Leica DM8000 microscope. The functionalization step will be repeated until full coverage is achieved. Frequency measurements will be conducted on the developed DAIS designs using IMM200 available in the team's research lab.

The prototypes will be tested in the team's FLOCON gas management system to establish the baseline when exposed to a dry nitrogen-only environment. The FLOCON gas management system is connected to a fume hood for safe operation and comprises gas lines, a controlled temperature system, mass flow controllers (MFCs) for regulating gas flow, bubblers for introducing liquid compounds, mixing chamber to ensure the uniformity of the flowing gas, and a designed test chamber for sensor prototype evaluations. The different VOC concentration levels are achieved by varying the gas flow rate using the MFCs to a target setting. Sensors' response times and sensitivities will be measured. Utilizing high purity nitrogen as the carrier gas, the VOCs are inlet through bubblers to the gas mixing chamber. This will allow sensor training under a well-controlled environment against lung cancer VOCs as well as background compounds found in healthy exhaled breath, as identified in aim A of this work.

Sensor functionality under various deposition condition and thicknesses will be evaluated while the test chamber temperature will be controlled for the entire duration of the test to ensure eliminating unforeseen environmental fluctuations from sensor evaluation. The measurement outcomes will then be used to fine tune the functionalization step, selecting appropriate materials from the list of developed materials for an array topology. A potential adjustment on the device fabrication step can also be accommodated. Sensor array will be fabricated at Angstrom and will be functionalized using the revised process and sensing material. In the signal processing and VOC identification step, a PCA model will be utilized that has already been developed in the PIs team with a preliminary measurement showing the ability to distinctly identify the target VOC. The PCA model will be optimized in this step based on the target VOCs from aim A and will be utilized for VOC pattern identification. Using FLOCON, the developed array prototype will be exposed to dry nitrogen for 1 hour to establish the baseline. The prototype will then be exposed to the gradual increase of the relative humidity and thereafter, carbon dioxide as the two common background elements. The sensor array prototype will then be exposed to the gradual and timed increase in the target VOC from aim A.

The prototype limit of detection as well as the device sensitivity will be evaluated. These results will be utilized in future steps to train sensor array for compound identification. The collected data will be safely saved on a University of Windsor server and will be password protected with access only provided to the designated research team.

This proposed work is closely aligned with the eligibility and evaluation criteria of this competition as well as the global call to action to develop sustainable approaches to health care through a comprehensive One-Health perspective. Upon successful completion of this research, the team will utilize the developed proof-of-concept to apply for the Lab-to-Market and the NSERC I2I grants to promote the technology commercialization and bring the benefit of the work to Canadians. In addition, the proposed research activity will have a broad impact on highly qualified personnel (HQP) training and significantly enhance collaboration between the research team and the major stakeholders in health.

Impact Statement

Lung cancer is one of the deadliest types of cancer, claiming tens of thousands of lives per year in Canada [1]. Delays in diagnosing lung cancer reduce the effectiveness of treatments, thus leading to greater morbidity and mortality [2]. Even though evidence shows the benefits of early-stage diagnosis, the routine screening of large numbers of people for early-stage lung cancer is currently impractical [3-5]. The high cost and complexity of the current procedures available to screen for the early stages of lung cancer limit their use for only modest numbers of patients at higher risk [6]. As a result, many early-stage lung cancer cases likely remain undetected until the disease advances to later stages. This leads to the use of more expensive and invasive treatment approaches to fight the disease after advanced progression, ultimately resulting in reduced survival rates [3-7]. The development of early-stage diagnostic and monitoring tools is essential to creating a sustainable, cost-effective and practical screening and surveillance program for lung cancer in the general population. Such early pre-emptive intervention will have a tremendous impact on the personal health and wellbeing of Canadians. This step, however, relies on developing new autonomous, portable, and most importantly sensitive early-stage technologies. An attractive new approach for lung cancer diagnosis relies on detecting disease biomarker substances in exhaled human breath [8-10]. During the early stages of lung cancer, patients exhale low concentration level, yet traceable -with advanced and emerging technologies- amounts of volatile organic compounds (VOCs) in the range of 10 – 200 ppm. Whereas a person without lung cancer will have the same VOCs in the 10 - 500 ppb range [11-13]. Over 42 VOCs have been proposed as candidate lung cancer biomarkers [14-15]. As such, novel approaches for lung cancer diagnosis and monitoring have been proposed through the analysis of candidate VOC profiles [13]. Conventionally a gas chromatography-mass spectrometry (GC-MS) system is used to identify and quantify VOC's. However, GC-MS and most available commercial gas sensors require sample collection as well as complex lab analysis. Furthermore, these systems are bulky with high power consumption, as well as strict limits on the range of operating temperatures and humidity [16-18]. These challenges prevent the use of this detection method for large-scale and routine cancer screening campaigns. An alternative method is to utilize high-performance micromachined sensor systems that are designed to be implemented and sustained in low-resource settings [19-21]. Their performance is evaluated by sensor characteristics including sensitivity, selectivity, limit of detection, reversibility, and response time [22-23]. In this multidisciplinary research work and in contrast with traditional gas sensors, a recently patented novel quartz crystal microbalance (QCM) with unique electrode configuration is proposed that operates based on distribution of area for improving mass sensitivity (DAIS) [24]. This work focuses on piloting this novel electronic nose technology using advanced microfabrication techniques. Unlike conventional detection methods, this technology extends the much-needed limit of detection for the high-performance detection of VOCs and biomarkers characteristic of early-stage lung cancer [25-28]. In addition, this technology offers batch production, which reduces the cost, provides tight parameter specification, and achievable system integration that are essential for routine clinical practices. The device level of miniaturization and power consumption, cost-efficiency, and potential for array fabrication as well as integration are considered key factors in the sensors' implementation. The adoption of the proposed new technology over the medium-term facilitates the technology transfer of urgently needed miniaturized, high performance, and cost-effective electronic nose systems for autonomous early detection of lung cancer target biomarkers at the application level. The potential for wirelessly transmitting and recording the proposed sensor's collected data will lead to significant advances in diagnostics, wellness assessment, and long-term monitoring of patients in remote areas to improve equity and sustainability in health care delivery for Canadians.

Title:

Micromachined Electronic Nose (e-Nose) Technology – A Paradigm Shift in Lung Cancer Early Detection

PI:

Dr. Arezoo Emadi, PI, Associate Professor at the Department of Electrical and Computer Engineering at UWindsor.

Public Summary

In 2024, lung cancer has continued to be identified as the leading cause of cancer deaths in Canada. While the Canadian Cancer Society estimates a lung cancer diagnosis for 1 in 14 Canadians in their lifetime, the absence of a wide-scale and safe lung cancer screening program in Canada significantly contributes to this rising problem when many lung cancer cases may go undetected until symptoms present at later stages. The unavailability of such an early detection tool is especially concerning as for lung cancer, the 5-year survival rate is drastically reduced from 62% for those diagnosed at stage I to only about 3% for stage IV. According to the World Health Organization, lung cancer patients diagnosed at the later stages are extremely hard to treat as the cancerous cells fail to respond to the chemotherapy treatment at later stages. As such, early detection of lung cancer is becoming an essential strategy for more effective and affordable health maintenance that can distinctly improve patient survival rates. Therefore, with the economic and emotional burden of lung cancer associated with the loss of lives and resources, there is a momentous need to evaluate low-cost approaches for early-stage screening, diagnosing, and monitoring. However, current technologies do not provide the sensitivity and throughput required to screen large numbers of people for early-stage disease. Using a recently developed technology, this interdisciplinary research work proposes to pilot and demonstrate the benefits and applicability of a recently patented electronic nose technology as an effective alternative candidate for early lung cancer detection. This electronic nose technology is built on detecting lung cancer biomarker substances in human breath.

In the short-term, the applicability and capabilities of this novel electronic nose technology will be demonstrated by precisely detecting previously validated lung cancer biomarkers in a controlled environment. The adoption of the proposed new technology in this work over the medium-term will facilitate the technology transfer of urgently needed miniaturized, high-efficiency, high performance, and cost-effective smart sensor systems, developed as a competitive production system for early detection of target biomarkers at the application level. Over the longer term, the team anticipates exploring the potential for wirelessly transmitting and recording the sensors collected data, leading to significant advances in diagnostics, wellness assessment, and long-term monitoring of patients in remote areas as a part of the team's goals to improve equity and sustainability in health care delivery.

The enhancement offered by this novel technology enables transformative breakthroughs in medical applications by constructing robust, real-time, safe, and non-destructive, portable, low-cost, and efficient medical imaging systems. This technique's critical values arise from its low cost, portability, and the absence of ionizing radiation, a strong magnetic field, and other known side effects, making it desirable for repeated harmless scans. These ultimately dictate the ease of accessibility for critical needs specifically for lung cancer detection where timely diagnosis and treatment monitoring is imperative.

Budget Detail

Salaries ($20,000)

It is anticipated that three highly qualified personnel (HQP) including one PhD student, and two Outstanding Scholar Undergraduate students will be trained and working on this research project over one year. The requested budget is to ensure support for students who will actively work on the different areas of this project. The stipend of PhD student from this grant is $20,000. The PhD student will be additionally supported through Graduate Assistantships ($12,000/year) available at the UWindsor beyond the requested fund in this project. Additionally, the University of Windsor offers graduate students entrance scholarships up to $7,500 per year. Two undergraduate students will also be recruited and trained in this project. These undergraduate students will be funded through the University of Windsor Outstanding Scholar program ($2,000/term).

The aspiration is to apply for NSERC Idea to Innovate by the end of the one-year project to pursue technology implementation.

Fabrication Fee ($3,000)

This requested funding covers the cost of electronic nose sensor prototype development at the cleanroom facility that includes daily access fees, and hourly rates for using the mask aligner, metal deposition, deep reactive ion etcher, and plasma enhanced chemical vapour deposition, as well as the costs of silicon wafers, SOI wafers, wafer carriers, chemical wet etchant, and physical mask making. The allocated budget will also cover the average mandatory payment for device packaging through CMC Microsystems.

Materials and Lab Consumables ($2,000)

The fund is to cover the cost for material development, sensor coating solutions as well as driving and read-out PCB circuitry, electrical components, and BNC cables. This fund will further cover the cost of lab consumables needed for prototype fabrication, and tests and evaluations. Lab consumables include probes, cables, connectors, gloves, lab coats and goggles, tweezers, tools and toolboxes, glassware, polymers, solvents, quartz substrate, and gas cylinders for FLOCON gas management system.

Publication ($0)

The team will publish their funding in peer-reviewed journals that will not have a mandatory charge. The team further publish and present their findings at conferences and symposium.

Travel, Conference, and Presentation ($0)

HQP are expected to attend and present the results of this work at a conferences and symposium. Internal travel funds for HQP are available through graduate students travel award at University of Windsor. The travel cost for the PI will be covered through her UWindsor travel and professional development funds as well as University of Windsor Faculty Travel Award.

Appendix

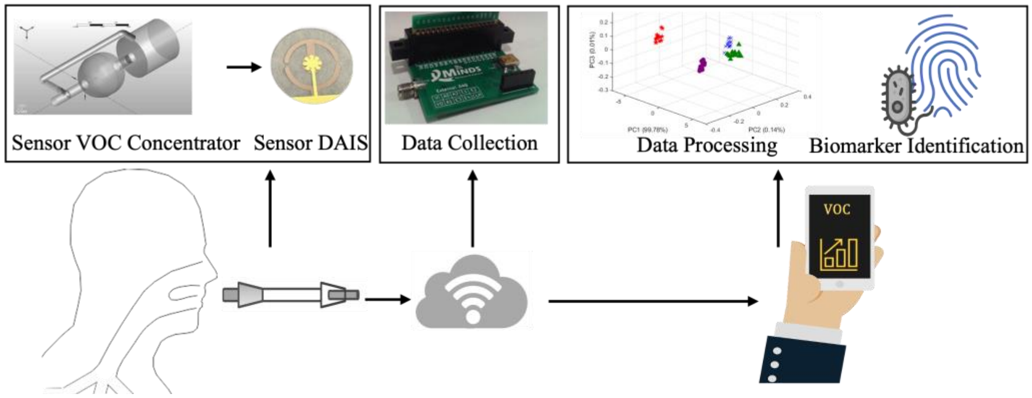


Figure 1: The proposed handheld electronic nose system utilizing high-sensitivity QCM DAIS sensing technology for early-stage lung cancer biomarker detection. The system includes three main components: a) a prototype VOC collector developed in PI's research team [27-28] that will be optimized for the lung cancer VOC concentration in this work, b) a patented high sensitivity micromachined sensor [24-26] developed in PI's team, and a data collector and transmitter, and c) a data processing model developed in PI's team to identify the target biomarkers [29].

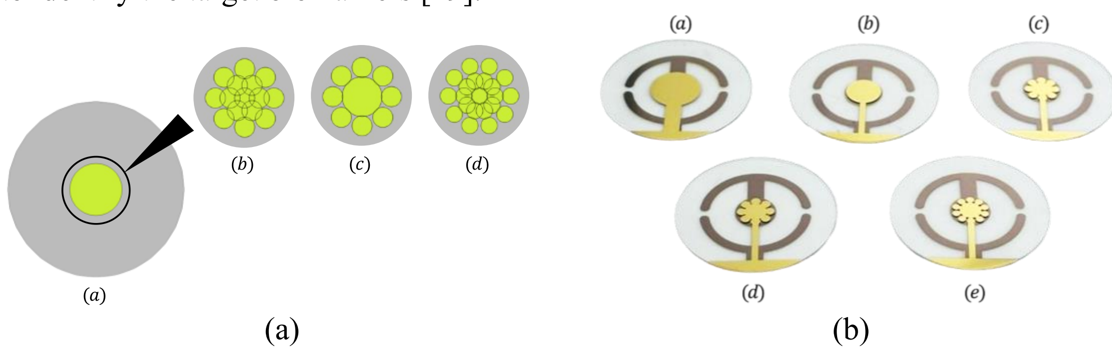


Figure 2: (a) Schematic of the newly developed QCMs utilizing DAIS approach featuring distinct designs derived from the simulation findings. (a) Novel circular-QCM, featuring a conventional circular electrode with a radius of 2.96 mm. (b) DAIS(G1)-QCM, (c) DAIS(G2)-QCM, and (d) DAIS(G3)-QCM maximize the energy trapping effect region by adopting array of smaller electrodes. (b) Fabricated prototype 5 MHz QCMs with varied topologies at Angstrom (a) Conventional-QCM (b) Novel circular-QCM (c) DAIS(G1)-QCM (d) DAIS(G2)-QCM (e) DAIS(G3)-QCM.

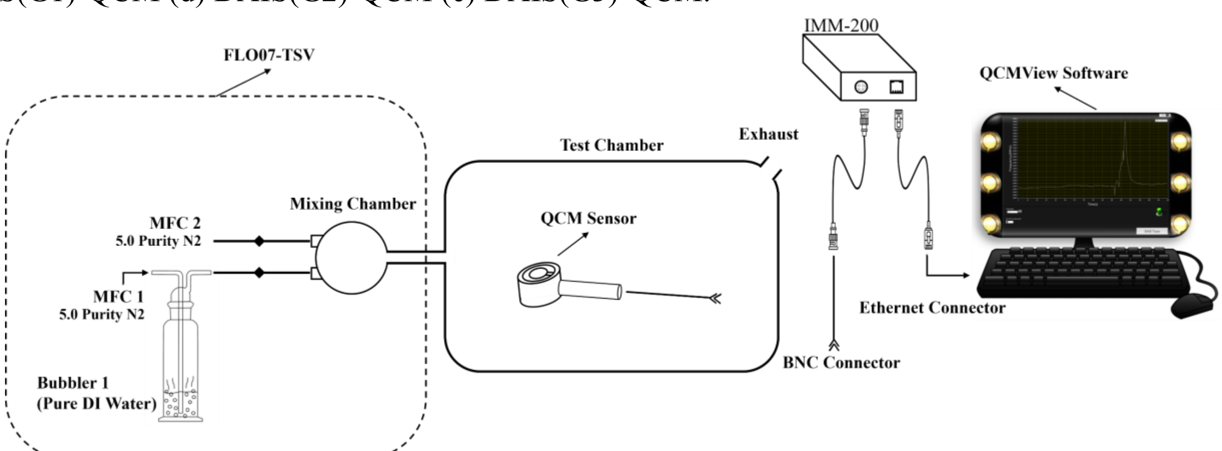
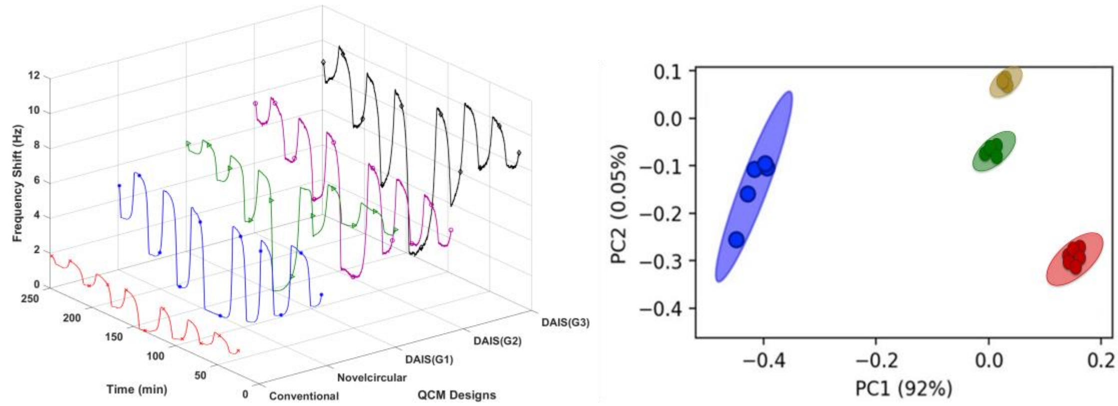


Figure 3: Schematic of the proposed experimental setup prior to integration, incorporating the Plasmionique FLO07-TSV for gas injection regulation into a test chamber, and the IMM-200 for acquiring the resonant frequency of the QCM sensor. The setup will be utilized for precise sensor training and data processing.



(a) (b)

Figure 4: (a) The graph from preliminary experiment results illustrates the responses of prototype QCMs to variations in selected analyte for proof of concept which is modulated to follow a distinct pattern comprising two cycles. (b) The preliminary PCA plots for the normalized sensor response for 4 different VOCs as proof of concept demonstrating the ability to clearly identify and differentiate between target VOCs in a complex environment utilizing the proposed approach in this work.

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Re: Support for Micromachined Electronic Nose (e-Nose) Technology – A Paradigm Shift in Lung Cancer Early Detection

Dear Members of the Evaluation Committee,

On behalf of the University of Windsor, I am delighted to confirm our strong support for the proposal being submitted to the Geoffrey Ogram Memorial Research Grant to develop an advanced micromachined electronic nose for early-stage lung cancer detection. This important initiative is of strategic value to the University of Windsor. It aligns seamlessly with our establishment of WE-SPARK Research Health Institute, an institutional initiative that supports and stives to address research and innovation challenges faced by our community in a close collaboration with Windsor-Essex Regional Hospital.

The "Micromachined Electronic Nose (e-Nose) Technology – A Paradigm Shift in Lung Cancer Early Detection" initiative will be led by Dr. Arezoo Emadi, an Associate Professor in the University of Windsor Department of Electrical and Computer Engineering, in collaboration with researchers from Department of Chemistry and Biochemistry, Biology, and WE-SPARK.

Dr. Emadi is an expert in the bio sensors, transducers, micro electromechanical systems, and advanced micro and nano fabrication technology that are at the core of this project. She has a track record of successful interdisciplinary collaboration that will help to bring the benefits of micromachining and electronic nose systems to the medical field, including a recently developed sensor technology for detecting virous as part of Integrated Network for the Surveillance of Pathogens (INSPIRE) to instill resilience in Canadian biomanufacturing and healthcare supply chains.

To help ensure the success of this important initiative when this proposal is successful, the University of Windsor Department of Electrical and Computer Engineering will provide two graduate assistantships for the eligible PhD student working on this research, a contribution valued at $12,000. In addition, the Faculty of Graduate Studies will provide up to $750 in conference travel support for the eligible graduate student that presents a paper at a conference. The graduate student hired into the program with GPA >80% may also be eligible to receive entrance scholarships of $7,500 in keeping with the Faculty of Graduate Studies admission policy. Moreover, the University of Windsor will fund two eligible undergraduate students in this program through Outstanding Scholar research fund, another contribution valued at $4,000/term.

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The University of Windsor is confident that this initiative will result in a new and innovative early-stage lung cancer detection technology while simultaneously providing rich and exciting research and training opportunities for the researcher and students involved. It is for these reasons that the University of Windsor strongly supports this proposal, and we urge you to do the same.

Sincerely,

Shanthi Johnson, PhD, RD, FDC, FACSM, FGSA

Vice-President, Research and Innovation

University of Windsor